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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/647,801 | 08/25/2003 | Dennis C. Liotta | 18085.105233CON1 (EMU 201 | 2351 |
| 20786 | 7590 | 05/17/2006 | EXAMINER MAIER, LEIGH C | |
| KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309 | | | ART UNIT 1623 | PAPER NUMBER |

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/647,801 | LIOTTA ET AL. | |
| | Examiner | Art Unit | |
| | Leigh C. Maier | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,10,12-16,18-22 and 29-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 72-85 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,10,12-16,18-22 and 29-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2006 has been entered.

Claims 1 and 66-71 are amended. Claims 72-85 are newly added. Claims 1, 3-5, 10, 12-16, 18-22, and 29-85 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 – 1st paragraph

Claims 1, 3, 5, 10, 12-16, 18-22, and 29-71 are again rejected under 35 U.S.C. 112, first paragraph, as set forth in the previous Office action.

Applicant's arguments filed February 27, 2006 have been fully considered but they are not persuasive.

Applicant discusses at length the difficulties in the use of sphingolipids, per se, and how they are improved by preparing them in the form of a prodrug by the covalent attachment of and R² substituent. While this may be a beneficial contribution to the art, it does not address the concern of the original enablement (scope) rejection. That is, the majority of the compounds

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claimed do not appear to have an adequate lipid portion that would make them actual sphingolipid “analogs” that would be expected to have the same activity as actual sphingolipids.

Applicant further contends that the specification provides biological activity of an exemplary prodrug. The examiner agrees that this is disclosed. However, it does have a substantial lipid portion as appears to be required by compounds having the recited activity. It is further noted that this exemplary compound is not encompassed by the formula of claim 1.

The specification suggests that the antiproliferative activity stems from the activity of the compounds as protein kinase c (PKC) inhibitors. The examiner agrees that the inhibition of PKC is correlated with treatment of diseases comprising abnormal cell proliferation, and PKC inhibitors are known and used in the art. Bell et al (US 4,937,232) teaches the inhibition of PKC with long-chain bases. See abstract and reference claims, for example. These are not the only type of inhibitor known. Grunicke et al (US 5,770,593) teaches the use of a variety of inhibitors. However, they all fall into the categories of polycyclics and lipids. See examples and col 2.

Finally, Applicant contends that by issuing the parent in the instant case, “the Patent Office has already found that the application is enabled for the compounds recited in the pending method claims.” The examiner agrees that they are all generally enabled for some credible utility. However, this utility does not have to be the one stated by Applicant. As noted before, some of the compounds apparently not enabled for the instant method would be perfectly enabled as intermediates for compounds that are enabled for this method. Furthermore, (oligo)saccharide derivatives are well known for anti-adhesive properties. The instant compounds would be useful in preparing multivalent oligosaccharide compounds, such as those taught by Simon et al (US 5,736,533). Finally, the fact the Applicant disclosed the compounds as

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being antiproliferatives, does not mean that this is the only credible activity that they might possess. Akimoto (of record) teaches compounds similar to those thought to be enabled having immunostimulant effects.

Allowable Subject Matter

Allowable subject matter is as set forth in the previous Office action. Newly added claims 72-85, depending from allowed claim 4, are also allowed.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
May 12, 2006